510(k) Summary – K123067

JAN 2 9 2013

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

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6. Date Prepared	Sept 28, 2012
7. Device Trade Name(s)	Hi-Torque Progress Guide Wire Family Hi-Torque Pilot Guide Wire Family
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device(s) Name(s)	HI-TORQUE PROGRESS Guide Wire (K091825, cleared Sept. 25, 2009) HI-TORQUE PILOT Guide Wire (K030549/K101116, originally cleared May14, 2003)

7.1 Device Description (HI-TORQUE PROGRESS)

The HI-TORQUE PROGRESS Guide Wire (K091825, cleared Sept. 25, 2009) is an existing family of guide wires, designed to provide improved torque response and crossing while maintaining tactile feedback in stenotic vessels. The subject wire is a core to tip design, where the core material runs through the entire length of the wire. This family of guide wires has a maximum diameter of 0.0140" with a stainless steel core and is provided in 190cm extendable and 300cm exchange lengths. The distal core segment of the PROGRESS guide wire family is offered in 5 configurations: PROGRESS 40, PROGRESS 80, PROGRESS 120, PROGRESS 140T and PROGRESS 200T. Each configuration is identical in design except for those design features that impact tip stiffness.

7.2 Device Description (HI-TORQUE PILOT)

The HI-TORQUE PILOT Guide Wire (K030549/K101116, originally cleared May14, 2003) is an existing family of guide wires constructed using a 304V stainless steel core. HI-TORQUE PILOT Guide Wires have a maximum diameter of 0.0140" and are available in 190cm extendable lengths and a 300 cm exchange length. There are three HI-TORQUE PILOT™ Guide Wire designs with varying tip stiffness (i.e., HI-TORQUE PILOT™ 50, HI-TORQUE PILOT™ 150, and HI-TORQUE PILOT™ 200 Guide Wires). The distal segment of the guide wire includes a series of tapered grinds and a flat section, which reduce the diameter and stiffness of the distal core, thus yielding the desired flexibility and performance.

7.3 Indication for Use (HI-TORQUE PROGRESS and HI-TORQUE PILOT)

Intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature. This guide wire may also be used to cross or assist in crossing *de novo* chronic total coronary occlusions (CTO).

7.4 Technological Characteristics

There have been no physical changes to the subject devices as compared to the currently marketed predicate devices except for a change in indication and related clinical information provided in the IFU and labeling. Comparisons of the technological characteristics such as product performance, design, and intended use between the subject and predicate devices show that they are substantially equivalent.

7.5 *In Vitro* Bench, Biocompatibility, Packaging and Sterilization Testing

There have been no physical changes to the subject devices as compared to the predicate devices except for a change in indication statement and related clinical information provided in the IFU and labeling. Comparisons of in-vitro bench, biocompatibility, packaging, and sterilization testing are not necessary. The subject and predicate devices are identical and in-vitro bench testing, biocompatibility, packaging and sterilization for the subject devices are therefore substantially equivalent to their respective predicate devices.

7.6 EXPERT CTO Guidewire Clinical Trial Summary

Objectives
The primary objectives of this trial are to:

- assess the safety and effectiveness of the HI-TORQUE (HT) PROGRESS and HT PILOT guide wires in recanalization of chronic total occlusions and
- assess the safety and effectiveness of the MINI TREK Coronary Dilatation Catheter in predilatation of chronic total occlusions.
- assess the safety and effectiveness of the XIENCE V, XIENCE nano, and XIENCE PRIME Everolimus Eluting Coronary Stent Systems for the treatment of chronic total coronary occlusions.

Although the guidewire and predilatation portions of the EXPERT CTO clinical trial are complete, the longer term safety and effectiveness results of the XIENCE V and XIENCE PRIME stent systems in the treatment of chronic total occlusions is ongoing. The MINI TREK predilatation results and XIENCE V and XIENCE PRIME results will be reported separately.

Trial Design

The EXPERT CTO is a prospective, multi-center, single-arm study. Approximately 250 subjects with signs and/or symptoms considered typical of ischemic heart disease attributed to a CTO are expected to be enrolled. Subjects will undergo elective, attempted CTO percutaneous revascularization.

For the initial 138 subjects enrolled, HT PROGRESS or HT PILOT guide wires (the study guidwires) were used in each case. Other, non-study guidewires may also have been used in each case at the discretion of the physician. Successful guide wire crossing was defined as confirmation of the presence of a guide wire in the distal true lumen. Guide wire subjects were followed through hospital discharge. The target lesions were predilated using a standard angioplasty balloon. For at least the initial 60 subjects with successful guide wire crossing, identified as confirmation of the guide wire in the distal true lumen, the MINI TREK Coronary Dilatation Catheter was to be used for the first predilatation attempt. The XIENCE V and/or XIENCE PRIME stents were to be used in all subjects

for whom recanalization and predilatation of the target lesion was completed. Stent subjects are to be followed through 5 years with follow-up at 30 days, 6 months, 1 year, and annually thereafter through 5-years.

7.7 Results

Primary Endpoint Analysis

The primary endpoint of successful recanalization of the CTO was achieved in 79.0% (109/138) of the subjects with a lower one-sided 95% confidence interval (CI) of 72.8%. The individual criteria for successful recanalization included: confirmation of placement of any guide wire in the distal true lumen in 89.9% (124/138) of the subjects and absence of in-hospital MACE (per ARC MI definition) in 89.1% (123/138) of the subjects.

Because the lower one-sided 95% CI is above the protocol-specified performance goal of 62.5% ($p<0.0001$), the study guide wire is considered to have successfully met its endpoint. Refer to **Table 7-2**

Table 7-2 Primary Endpoint Results – All Guidewires

	Guide Wire Success	Two-sided 95% CI	Performance Goal	Lower Bound of one-sided 95% CI	P-value
Guide Wire-related Endpoint	79.0% (109/138)	[71.2%,85.5%]	62.50%	72.8%	<0.0001
Confirmation of placement of any guide wire in the distal true lumen	89.9% (124/138)	[83.6%,94.3%]	--	--	--
Absence of in-hospital MACE**	89.1% (123/138)	[82.7%,93.8%]	--	--	--

** Based on ARC MI.

To allow for a more meaningful comparison to literature, an alternate analysis of the primary endpoint was performed. The successful recanalization rate was calculated using the MI *per protocol* definition for the second component of absence of in-hospital MACE. , Successful recanalization of the CTO was achieved in 87.7% (121/138) of the subjects with a lower one-sided 95% CI of 82.3%. **Table 7-3** shows the results of the alternate analysis of the primary endpoint. The individual criteria for successful recanalization included: confirmation of placement of the guide wire in the distal true lumen in 89.9% (124/138) of the subjects and absence of in-hospital MACE (*per protocol* MI definition) in 97.8% (135/138) of the subjects. The lower bound of the one-sided 95% CI of the primary endpoint in the secondary analysis is approximately 20% above the protocol-specified performance goal of 62.5% ($p<0.0001$).

Table 7-3 Alternate Analysis of the Primary Endpoint
(MACE Includes *Per Protocol* Definition of MI)

	Guide Wire Success	Two-sided 95% CI	Performance Goal	Lower Bound of one-sided 95% CI	P-value
Guide wire-related Endpoint	87.7% (121/138)	[81.0%,92.7%]	62.50%	82.3%	<.0001
Confirmation of placement of any guide wire in the distal true lumen	89.9% (124/138)	[83.6%,94.3%]	--	--	--
Absence of in-hospital MACE**	97.8% (135/138)	[93.8%,99.5%]	--	--	--

** Based on *per protocol* MI

Table 7-4 shows the results for the alternate analysis for the study guidewires only.

Table 7-4 Alternate Analysis of the Primary Endpoint Results
(Confined to Study Guide-Wires, MACE Includes *Per protocol* Definition of MI)

	Guide Wire Success	Two-sided 95% CI
Guide wire-related Endpoint	58.0% (80/138)	[49.3%,66.3%]
Confirmation of placement of the study guide wire in the distal true lumen	60.1% (83/138)	[51.5%,68.4%]
Absence of in-hospital MACE**	97.8% (135/138)	[93.8%,99.5%]

7.8 Clinical Summary Conclusion

The EXPERT CTO clinical trial and results demonstrate that the study guide wires, HI-TORQUE PROGRESS and HI-TORQUE PILOT families, were successfully used to treat chronic total coronary occlusions and that the primary and secondary endpoints of the guide wire portion of the study were met, and therefore support a CTO indication for these wires. No new safety or effectiveness issues were raised during the testing program and, therefore, these devices may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Abbott Vascular, Inc.
C/O Mr. Sean Mullin
26531 Ynez Road
Temecula, CA 92589

JAN 29 2013

Re: K123067
Trade/Device Name: Hi-Torque Progress Guide Wire Family and Hi-Torque Pilot Guide Wire Family
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 14, 2012
Received: December 17, 2012

Dear Mr. Mullin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number(s) (if known): K123067

Device Name(s): **Hi-Torque Progress Guide Wire Family**
Hi-Torque Pilot Guide Wire Family

Indications for Use: Intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature. This guide wire may also be used to cross or assist in crossing *de novo* chronic total coronary occlusions (CTO).

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123067